

## **REMARKS**

Reconsideration of this Application and entry of this Amendment are respectfully requested.

### **Status of the Claims**

Claims 1-23 are pending. Claims 1-4, 6-9, 13, 15-18, 22 and 23 are rejected. Claims 5, 10-12, 14 and 19-21 are objected to.

Claims 1-4, 6 and 7 have been amended in response to a rejection for indefiniteness. Claim 10 has been amended to correct a punctuation error. No amendments have been made to distinguish the claims over cited prior art references.

### **Objections to the Specification**

The Abstract of the disclosure has been objected to as containing sentences that do not describe the present invention. Applicants have amended the Abstract herein to delete the sentences that were objected to, and request that this objection be withdrawn.

Applicants have also amended paragraph 0010 of the specification to correct a typographical error in the last sentence.

### **Objections to the Claims**

Claim 10 has been objected to for the lack of a period at the end of line 2. Applicants have amended claim 10 in response to this objection, and request that the objection be withdrawn.

### **Rejections Under 35 U.S.C. § 112**

Claims 6 and 7 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants have amended claims 6 and 7 in response to this rejection. Claim 1 has also been amended to recite "a first monofilament wire-form" to create a clarified antecedent basis for claim 6. Claims 2-4 have been amended to refer to the first

wire-form recited in parent claim 1. In response to the aforementioned amendments, Applicants request that this rejection be withdrawn.

### **Rejections Under 35 U.S.C. § 102**

Claims 1-4, 8 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,342,300 to Stefanadis *et al.*, hereinafter "Stefanadis." The Examiner asserts, *inter alia*, that Stefanadis teaches an apparatus including

"a monofilament wire-form **9** having . . . an expanded configuration preformed with multiple lobes **3** arranged in a radially symmetrical staggered sequence along the center line of the catheter **1** (Fig. 2)," and "each lobe extends from the center line to an apex engageable with the lumen of the body vessel (Fig. 3)."

Applicants respectfully disagree with the above characterization of the teachings of Stefanadis and traverse this rejection there under. Claim 1 requires that "each lobe extends from the center line to an apex engageable with the lumen of the body vessel." Lobes, as defined in the Application, extend radially outward from a starting segment adjacent the catheter center line, to an apex, then continue radially inward to an ending segment adjacent the catheter center line (See paragraph 0008). Lobes are also commonly defined as "a rounded projection, especially a rounded, projecting anatomical part: the lobe of an ear (The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2003 by Houghton Mifflin Company)".

Stefanadis teaches a stent catheter having a helix or spiral **2** expandable about the catheter into continuous contact with a vessel wall (column 3, lines 5-11). Stefanadis' turns **3** are portions of geometrically defined Archimedian or conical spirals, which have constant or diminishing radii, respectively, along their length. Only the two ends of spiral **2**, not each of turns **3**, contact catheter shaft **1**; Thus, turns **3** cannot be considered multiple lobes extending from the catheter center line, as required by claim 1. Additionally, since turns **3** are radially distant from the catheter shaft of Stefanadis, the

portion of the catheter between the ends of spiral 2 cannot be centered in the vessel by turns 3. Thus, the invention defined by claim 1 is both structurally and functionally distinct from the teachings of Stefanadis.

As described in paragraph 0009, "the designation 'staggered' means that each lobe 50 extends in a different radial direction from adjacent lobe(s) 50." Stefanadis' turns 3 also cannot be considered to teach lobes arranged in a "staggered sequence along the center line of the catheter," as required in claim 1. For the reasons described above, Stefanadis fails to anticipate claim 1 because the reference does not teach all the limitations of the claim.

Claims 2-4, 8 and 9 depend directly or indirectly from claim 1 and are patentable for at least the reasons described above with respect to claim 1. Additionally, Stefanadis fails to teach that "the lobes are generally disposed in at least two radial directions extending through the center line," as required in claim 8.

Claims 1-4, 8, 9, 13, 15-18, 22 and 23 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,074,339 to Gambale *et al.*, hereinafter Gambale. Applicants traverse the rejection of independent claims 1 and 13 for the same reasons as those described above with respect to Stefanadis; That is, Gambale teaches a helix or spiral expandable about a catheter shaft. Gambale does not teach lobes as defined in the application or a common dictionary, nor does Gambale teach a staggered arrangement of lobes. Thus, Gambale fails to teach all the limitations of at least claims 1 and 13.

Claims 2-4, 8 and 9 depend directly or indirectly from claim 1 and are patentable over Gambale for at least the reasons described above with respect to claim 1. Additionally, Gambale fails to teach that "the lobes are generally disposed in at least two radial directions extending through the center line," as required in claim 8.

Claims 15-18, 22 and 23 depend directly or indirectly from claim 13 and are patentable over Gambale for at least the reasons described above with respect to claim

13. Additionally, Gambale fails to teach that "the lobes are generally disposed in at least two radial directions extending through the center line," as required in claim 17.

**Allowable Subject Matter**

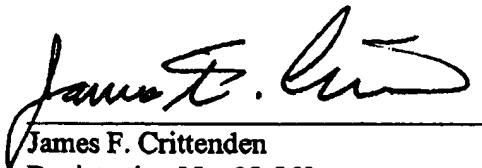
Applicants gratefully acknowledge the Examiner's indication of conditional allowability of claims 5-7, 10-12, 14 and 19-21.

**Conclusion**

Applicant believes that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner feels that a telephone conference would, in any way, expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone number (978) 739-3075 (EDT).

Dated this 29th day of November, 2004.

Respectfully submitted,



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